

Preoperative irradiation for prophylaxis of ectopic ossification after hip arthroplasty

A randomized study in 62 hips

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62 hips in 57 patients who were all considered to be at risk for ectopic bone formation were randomly divided into two groups: one control group and one group who received single dose radiotherapy of 5 Gy at the operation field preoperatively.

With a mean follow-up of 2.5 years, the incidence of heterotopic ossification in the control group was 16 of the 19 hips and in the irradiated group 6 of the 43 hips ($p = 0.001$).

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The reported incidence of ectopic bone formation after arthroplasty varies from 30% to 80% of the patients (Maloney et al. 1991, Thomas 1992). The process of ossification appears within 1 day–1 week after surgery and the triggering factor is still unknown (Kantorowitz et al. 1990, Goel and Sharp 1991, Pellegrini et al. 1992).

Irradiation and NSAIDs seem to be the only two effective prophylactic treatments (Gebuhr et al. 1991, Kjaersgaard-Andersen et al. 1991, Head et al. 1992). Although NSAIDs have satisfactory results, there are also disadvantages. A disadvantage with NSAID may be delayed bone healing and interference with ingrowth into noncemented components (Maloney et al. 1991). It also may induce side-effects in the central nervous system and the gastrointestinal tract (Gebuhr et al. 1991).

Postoperative irradiation prevents heterotopic ossification (Coventry and Scanlon 1981, Ayers et al. 1986, Lo et al. 1988, Maloney et al. 1992, Pellegrini et al. 1992). Kantorowitz et al. (1990) mentioned the possibility of preoperative irradiation but found no similar results between a 1-hour preoperative group and a postoperative group.

We evaluated the effect on ectopic bone formation, caused by a single 5 Gy dose of limited field radiation given one day before hip arthroplasty.

Patients and methods

62 primary or revision total hip arthroplasties were performed in 57 patients from January 1989 to Sep-

tember 1992, all by the same orthopedic surgeon. The mean age was 66 (24–80) years and 17 were men. The inclusion criteria were patients who did not use NSAIDs and were considered to be at risk for the development of ectopic bone (Table 1). All patients signed the informed consent form and the study was approved by the Ethics Committee at our hospital.

Arthroplasty was performed using two types of femoral components. The cemented SP-II prosthesis was used in 36 patients and the uncemented Zweimuller prosthesis in 26, both with an uncemented Protek-cup. The posterolateral approach was used in all patients.

The patients were randomly divided into two groups. We expected that at least 33% of the control group would develop ectopic ossification and a reduction to 15% in the irradiated group. In accordance with Hsieh (1992) and Fleiss (1981), who compared samples of unequal sizes, we allocated one third of

Table 1. Risk classification

Risk classification	Control group (19 hips)	Irradiation group (43 hips)
Hypertrophic arthrosis	10	27
Diffuse idiopathic skeletal hyperostosis	2	6
Ankylosing spondylitis	1	1
Active spondylitis ankylopoietica	1	0
Traumatic arthritis	1	5
Previous heterotopic ossification		
Ipsilateral (revision)	1	2
Contralateral	3	2

Table 2. Prevalence of ossification in the control group (Ctr) and irradiation group (Irr)

Grade	Cemented (n 36)		Uncemented, (n 26)		Total (n 62)	
	Ctr	Irr ^a	Ctr	Irr ^a	Ctr	Irr ^a
0	2 ^c	19 ^b	1	18 ^b	3	37 ^b
I	2	5	2	0	4	5
II	4	0	0	0	4	0
III	1	1	4	0	5	1
IV	2	0	1	0	3	0
Total	11	25	8	18	19	43

^a p < 0.001 (control vs. irradiated; grade 0 vs. grades I–IV)

^b p < 0.001 (irradiated grade 0 vs. irradiated grades I–IV)

^c p < 0.001 (control grade 0 vs. control grades I–IV)

the patients to group 1 (control) and the remaining two thirds to group 2 (irradiated). This reduced the number of patients needed for the study. The patients were randomly divided into three groups and two groups were put together.

The control group consisted of 11 women, who underwent 13 operations, and 5 men, who had 6 operations. The irradiated group consisted of 29 women, who had 30 operations, and 12 men with 13 operations. The groups showed no significant difference in age, sex and specific risk factors, when divided into cemented and uncemented (Tables 1 and 3).

The irradiation took place one day before the operation. A single dose of 5 Gy limited field radiation was delivered through anterior and posterior fields that were centered on the collum of the femur, with an area of 10 by 10 cm.

Postoperatively, the patients were radiographically examined every 6 months, with an average follow-up of 31 (19–62) months. Ectopic ossification was classified according to Brooker et al. (1973). Statistical analysis was performed with the chi-square and log-rank test.

Results

14 of the 19 patients in the control group had ectopic bone formation and in the irradiated group 6 of the 43 patients had it (p < 0.001). Both the cemented and uncemented prostheses showed less ectopic bone formation in the irradiated groups (Table 2). One patient in the irradiated group had a superficial wound infection. This patient also developed ectopic bone, grade III.

Table 3. Mean age, years

	Control group	Irradiation group	Total
Cemented	72 (63–78)	70 (49–80)	70 (49–80)
Uncemented	61 (52–74) ^a	56 (24–63) ^a	57 (24–74) ^a
Total	68 (52–78)	63 (24–80)	65 (24–80)

^a p < 0.001 (cemented vs. uncemented)

Discussion

We found that a low dose of radiation did not reduce the efficacy of the prophylaxis more than treat with higher doses (Kantorowitz et al. 1990). The use of prophylactic single low-dose radiation has several advantages: the handling of the patient for radiation therapy is impracticable immediately after surgery and the therapy is regional rather than systemic, as with NSAIDs. A single low-dose irradiation has not been found to carry a risk of inducing sarcoma (Kim et al. 1978, Coventry and Scanlon 1981, Ayers et al. 1986, Kantorowitz et al. 1990).

There was no ectopic bone formation in the irradiated uncemented group. These patients were significantly younger than those in the cemented groups (Table 3). This implies a probable connection between age and the decreased incidence of ectopic bone formation in irradiated uncemented hips, which was already mentioned by Head et al. (1992).

Our findings imply that a single dose of 5 Gy given one day preoperatively is a safe and effective prophylaxis, for both cemented and uncemented prostheses, in the prevention of heterotopic ossification.

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